AMENDMENT AND REQUEST FOR RECONSIDERATION
UNDER 37 C.F.R. §1.111
U.S. Appln. No.: 09/077,606

REMARKS

Claims 43, 44, 46, 48, 49, 51-59, 61, 62, 64, 66, 67, 69, 72-79, and 82-109 are pending. Claims 76, 86, 90, 91, 95, and 97-109 have been rejected. Claims 76, 86, 95 and 97-105 have been amended to recite a pharmaceutical excipient, as supported by page 18, lines 4-9. Claims 43, 44, 46, 48, 49, 51-59, 61, 62, 64, 66, 67, 69, 72-79, and 82-109 remain in the case.

In the current Action, claims a rejection of claims 76, 86, and 97-105 is maintained because pharmaceutically inert carriers are described in conjunction with antibodies, not peptides. In addition, a rejection of claim 95 under Section 102(b) is maintained, since claim 95 does not recite a pharmaceutically inert carrier. Rejections under Section 102(b) of claims 76, 86, and 97-105 have been withdrawn based on the recitation of "pharmaceutically inert carrier."

The term pharmaceutically inert carrier has been replaced in claims 76, 86, and 97-105 by the term "pharmaceutical excipient" as supported on page 18 of the specification, and the same term has been added to claim 95. The SDS-PAGE gel of Glass *et al.* would not fall within the scope of a pharmaceutical excipient as presently claimed. As previously noted, the SDS-PAGE gel of Glass *et al.* causes mice to form adhesions that can make aseptic removal of the spleen difficult." A pharmaceutical excipient, on the other hand, would not encompass a material known to have an adverse affect.

Attached to this response is an excerpt from the International Pharmaceutical Excipient Council web site. This site defines excipients as "substances other than the pharmacologically active drug or prodrug which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form." They are classified by the functions they perform in a pharmaceutical dosage form, and principal excipient classifications (functions) include those binders, disintegrants, fillers (diluents), lubricants, glidants (flow enhancers), compression aids, colors, sweeteners, preservatives, suspensing/dispersing agents, film formers/coatings, flavors, and printing inks. While no

longer looked on as totally inert, they cannot do not have affects that are adverse in the general population. Thus, as noted in the appended article "Restocking the Excipient Superstore" from *Pharmaceutical Formulation and Quality*: "Excipients are now looked upon less as "inert" ingredients and more as the means by which active drugs can be made optimally effective, and it is out of this attitudinal change that the term "functional excipient" emerges." Certainly, SDS-PAGE gel is not a substance that makes an active drug "optimally effective." Therefore, absent compelling evidence that SDS-PAGE gel would be considered by those of skill in the art to be a pharmaceutical excipient, for example, by showing that SDS-PAGE gel is listed the United States Pharmacopeia National Formulary as an excipient, the Section 102 rejections based on Glass *et al.* must fail.

Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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Date

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

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MARKED-UP VERSION OF AMENDED CLAIMS

Please amend claims 76, 86, 95 and 97-105 as follows:

76. (Thrice Amended) A therapeutic agent for stimulating the immune system comprising an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:5, and a [pharmaceutically inert carrier] pharmaceutical excipient.

86. (Thrice Amended) A therapeutic agent for stimulating the immune system comprising an isolated peptide or protein and a [pharmaceutically inert carrier] pharmaceutical excipient, wherein the amino acid sequence of SEQ ID NO:5 comprises the amino acid sequence of the peptide or protein, wherein the peptide or protein has lectinic properties, and wherein the peptide or protein is recognized by an antibody specific to an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:5.

95. (Amended) A therapeutic agent for stimulating the immune system comprising an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:5, in monomer or dimer form, and a pharmaceutical excipient.

97. (Amended) A method of stimulating the immune system, comprising administering, to a subject in need of such stimulation, an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:1, and a [pharmaceutically inert carrier] pharmaceutical excipient.

98. (Amended) A method of stimulating the immune system, comprising administering, to a subject in need of such stimulation, an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:3, and a [pharmaceutically inert carrier] pharmaceutical excipient.

99. (Amended) A method of stimulating the immune system, comprising administering, to a subject in need of such stimulation, an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:4, and a [pharmaceutically inert carrier] pharmaceutical excipient.

100. (Amended) A method of stimulating the immune system, comprising administering, to a subject in need of such stimulation, an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:5, and a [pharmaceutically inert carrier] pharmaceutical excipient.

101. (Amended) A method of stimulating the immune system, comprising administering, to a subject in need of such stimulation, an isolated peptide or protein having lectinic properties and comprising the amino acid sequence of SEQ ID NO:6, and a [pharmaceutically inert carrier] pharmaecutical excipient.

102. (Amended) A therapeutic agent as claimed in claim 70, additionally comprising [an inert pharmaceutical carrier] pharmaceutical excipient.

103. (Amended) A therapeutic agent as claimed in claim 72, additionally comprising [an inert pharmaceutical carrier] a pharmaceutical excipient.

104. (Amended) A therapeutic agent as claimed in claim 74, additionally comprising [an inert pharmaceutical carrier] a pharmaceutical excipient.

105. (Amended) A therapeutic agent as claimed in claim 78, additionally comprising [an inert pharmaceutical carrier] a pharmaceutical excipient.

1. What are pharmaceutical xcipients?
Pharmaceutical excipients are substances other than the pharmacologically active drug or prodrug which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form. [Top]

2. How are pharmaceutical excipients classified?
They are classified by the functions they perform in a pharmaceutical dosage form. Principal excipient classifications (functions) are the following:

- Binders
- Disintegrants
- Fillers (diluents)
- Lubricants
- Glidants (flow enhancers)
- Compression aids
- Colors
- Sweeteners
- Preservatives
- Suspensing/dispersing agents
- Film formers/coatings
- Flavors
- Printing inks

[Top]

3. Why are excipients important in a drug product?
For many reasons. Some, for example, comprise the product's delivery system. These transport the active drug to the site in the body where the drug is intended to exert its action. Others will keep the drug from being released too early in the assimilation process in places where it could damage tender tissue and create gastric irritation or stomach upset. Others help the drug to disintegrate into particles small enough to reach the blood stream more quickly and still others protect the product's stability so it will be at maximum effectiveness at time of use. In addition, some excipients are used to aid the identification of a drug product. Last, but not least, some excipients are used simply to make the product taste and look better. This improves patient compliance, especially in children. Although technically "inactive" from a therapeutic sense, pharmaceutical excipients are critical and essential components of a modern drug product. In many products, excipients make up the bulk of the total dosage form. [Top]

release therapies show a great deal of promise in improving the outcome of drug therapies.

This recognition has resulted in a greater concern for the impact excipients can have on drug products and a greater interest in the possibilities in areas such as sustained-release polymer formulations. Excipients are now looked upon less as "inert" ingredients and more as the means by which active drugs can be made optimally effective, and it is out of this attitudinal change that the term "functional excipient" emerges.

Innovation and Established Science

Ironically, though, just as excipients are gaining more general recognition for what they can do for a dosage form, the excipients market seems to be, from one point of view, in stasis. Few wholly new excipients have been introduced into common use of late, and in oral dosage forms, still the "king" of drug delivery systems and by far the destination of the greatest volume of excipients, there have been very few new excipients since the 1970s. This state of affairs does not mean that excipient manufacturers and pharmaceutical formulators are moribund, however. Both have shown a great deal of ingenuity in developing and utilizing new, proprietary combinations of existing excipient chemistries (microcrystaline cellulose co-processed with silicone dioxide, for instance) to achieve new sets of functionalities. But as the much anticipated new actives emerge, new types of excipients will be needed for medicine to best utilize them, and the structural factors which have mitigated against new excipients will have to be overcome.

Some in the pharmaceutical business look upon the slow growth in the number of excipients as an indication of the usefulness and flexibility afforded by the 200 or so excipients now in common use. "Excipients represent a field that has matured," says Tony Palmieri of Pharmacia & Upjohn of Kalamazoo, MI. "The excipients we have now are pretty good. It is not to degrade the science of formulation to say